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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/804,893	03/13/2001	Susan Ann Bevers	11543.120	3883
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KUDIRKA & JOBSE, LLP
ONE STATE STREET
SUITE 1510
BOSTON, MA 02109

EXAMINER

EPPERSON, JON D

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 03/28/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary*File Copy*

Application No.

09/804,893

Applicant(s)

BEVERS ET AL.

Examiner

Jon D Epperson

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 1-16, 18, 20, 23 and 25-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17, 19, 21, 22 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4-6 6) ☐ Other: _____

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DETAILED ACTION

Please note: The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to **Group Art Unit 1639**.

Status of the Application

1. Receipt is acknowledged of a Response to a Restriction Requirement, which was dated on December 18, 2002 (Paper No. 11).

Priority Claims

2. The priority filing date of March 14, 2000 is acknowledged for 60/189,264.

Status of the Claims

3. Claims 1-33 are pending in the present application.
4. Applicant's response to the Restriction and/or Election of Species requirements in Paper No. 11 is acknowledged (Applicants elected Group XX i.e., claims 17, 19, 21-24) and claims 1-16, 18, 20 and 25-33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim (see below i.e., *Response to Restriction and/or Election of Species*).

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5. Please note: Applicant's *specifically* elected species (D and L corresponding to B-(-L-(D)_m)_n) was searched and was not found in the prior art. Thus, the search was expanded to non-elected species, which *were* found in the prior art, see rejections below. Also, see MPEP § 803.02 (emphasis added):

On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. *The prior art search, however, will not be extended unnecessarily to cover all nonelected species.* Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action made final. Amendments submitted after the final rejection further restricting the scope of the claim may be denied entry.

6. Please note: Applicant's elected species (biomolecule (B) = nucleic acid) was found in the art, see rejections below. Applicant is reminded of MPEP § 803.02 with respect to species elections:

On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species. Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action made final. Amendments submitted after the final rejection further restricting the scope of the claim may be denied entry.

7. Claim 23 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected species, the requirement having been traversed in Paper No. 6 (see below i.e., Response to Restriction and/or Election of Species).

8. Therefore, claims 17, 19, 21-22 and 24 are examined on the merits in this action.

Response to Restriction and/or Election of Species

9. Applicant's election with traverse of Group XX (claims 17, 19 and 21-24) in Paper No. 11 is acknowledged.

10. The traversal is on the ground(s) that "a method using a reactive dye molecule D which is a radical of a photostable visible dye, even though structurally different D (and L and B) components are possible, will not require different reaction steps to effect the claimed method which is contacting a biomolecule with the reactive dye as generically claimed."

11. These arguments were fully considered but were not found persuasive. The methods are distinct because they use different steps, require different reagents and/or will produce different results. The Examiner contends that different reaction steps will be needed to make and use the different claimed B-L-D compounds. Furthermore, the different compounds that are used in the different methods can be separately classified and, as a result, would constitute separate and burdensome searches.

12. Applicant's election of species in Paper No. 11 with traverse is also acknowledged.

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13. The traversal is on the ground(s) that “a method using a reactive dye molecule D which is a radical of a photostable visible dye, even though structurally different D (and L and B) components are possible, will not require different reaction steps to effect the claimed method which is contacting a biomolecule with the reactive dye as generically claimed.”

14. These arguments were fully considered but were not found persuasive. The Examiner's position is that the species are distinct, each from the other, because the structures and modes of action of each of the species encompassed are different. They would also differ in their reactivity and/or mechanism and/or the products made. Moreover, the method of adding a label to each species of biomolecule would be different. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

Furthermore, the Examiner previously stated that should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. This has not been done.

15. As a result, the restriction requirement and/or election of species is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

16. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98 (b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, “the list may not be

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incorporated into the specification but must be submitted in a separate paper.” Therefore, unless the references have been cited by the examiner on the form PTO-892, they have not been considered.

17. The references listed on applicants’ PTO-1449 forms have been considered by the Examiner. Copies of these forms are attached to this Office Action.

18. The information disclosure statement (Paper Nos. 4 and 6) fail to fully comply with 37 CFR 1.98(a)(3) because they do not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language. They have been placed in the application file, but the information referred to therein with respect to the non-English language documents of Langhals et al (WO 00/23446) and Langhals (DE 40 18 830) have not been considered.

Specification

19. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant’s cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claims Rejections - 35 U.S.C. 112, second paragraph

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

20. Claims 17, 19, 21-22 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. For **claim 17**, the phrase “wherein the linear atoms in L ... optionally can be included in a ring” is vague and indefinite. For example, it is not clear how the “linear” atoms could still be classified as “linear” if they are optionally included in a ring? Applicants are requested to clarify. Therefore, claims 17 and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.

B. For **claim 17**, the phrase “provided that D is not unsubstituted perylenyl” is vague and indefinite. For example, it would appear to the perylenyl would necessarily have to be substituted with a linker in order to bind to the biomolecule and, as a result, the peryleneyl would always be substituted. Applicants are requested to clarify. Therefore, claims 17 and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.

Claims Rejections - 35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

21. Claims 17, 19, 21-22 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Bevers et al (Bever, S.; O'Dea, T. P.; McLaughlin, L. W. "Perylene- and Naphthalene-based linkers for duplex and triplex stabilization" *J. Am. Chem. Soc.* **1998**, *120*, 11004-11005) (IDS is B11).

For *claims 17, 19, 21-22 and 24*, Bevers et al (see entire document) discloses a method for tethering a perylene bisimide to DNA wherein the perylene was joined via a straight chain linker to two phosphate oxygens of DNA (see Bevers et al, page 11004, paragraph 3, figures 1 and 2, wherein the hydroxyl on the linker, L, was converted into a reactive N,N-diisopropyl- β -cyanoethoxy phosphoramidite, X, which was subsequently bound to the DNA biomolecule, B, wherein the biomolecule was "detected" during the melting studies using absorption measurements), which anticipates claims 17, 19, 21-22 and 24.

22. Claims 17, 19, 21-22 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Suzuki et al (EP 0 808 829 A1) (Date of publication is **November 26, 1997**) (See IDS).

For *claims 17, 19, 21-22 and 24*, Suzuki et al (see entire document) discloses a nucleic acid detection method wherein polycyclic fluorescent labels are covalently

attached to the nucleic acid via a reactive carbodiimide group and a straight chain linker (see Suzuki et al, Detailed Description of Invention, especially compounds on pages 9-14), which anticipates claims 17, 19, 21-22 and 24.

23. Claims 17, 19, 21-22 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Balakin et al (EP 0 808 829 A1) (Date of publication is **November 26, 1997**) (See IDS).

For *claims 17, 19, 21-22 and 24*, Balakin et al (see entire document) discloses conjugates of pyrene and perylene with oligodeoxynucleotides for the detection of said oligodeoxynucleotides wherein said pyrene and perylene conjugates are attached to the nucleic acid via a linker wherein a reactive ester is used to attach said fluorophore to the nucleic acid (see Balakin et al, Results and Discussion Section, especially figures 2, 5, 7-13), which anticipates claims 17, 19, 21-22 and 24.

24. Claims 17, 19, 21-22 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Kool et al (US Patent No. 6,479,650) (Filing Date is **December 14, 1999**).

For *claims 17, 19, 21-22 and 24*, Kool et al (see entire document) discloses a method for visually detecting nucleic acids using fluorescent cyclic compounds joined to a carbon of a sugar molecule, anticipates applicants elected formula i.e., $B-(-L-(D)_m)_n$ wherein m and n are 1, B is a nucleic acid and L is a sugar analogue and D is any of the polycyclic compounds listed in the specification of '650 including a perylene imide-

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derivative (see Kool et al, Summary of Invention; see also column 3, paragraphs 4-7 and paragraph bridging columns 3-4; see also compounds listed in columns 6-14; see especially compound in column 9, lines 15-30; see also abstract indicating the use of phosphoramidites i.e., an X group that would enable the attachment to a hydroxy i.e., the DNA, which is a nucleic acid), which anticipates claims 17, 19, 21-22 and 24.

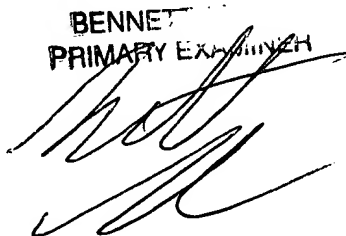
Contact Information

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (703) 308-2423. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

26. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

27. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-2439.

Jon D. Epperson, Ph.D.
March 20, 2003

BENNET
PRIMARY EXAMINER


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